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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 08/836,576 | 09/09/97 | HAENSLER | 0725-0100000 |

18M1/1223
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| EXAMINER BRUMBACK, B |
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| ART UNIT 1815 | PAPER NUMBER |
|------------------|--------------|

DATE MAILED: 12/23/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/836,576

Applicant(s)

Haensler et al.

Examiner

Brenda Brumback

Group Art Unit

1815



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-24 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The examiner acknowledges receipt of the Information Disclosure Statement on 10/17/97.

Specification

2. The specification lacks continuation data for the International Application PCT/FR95/01495. An appropriate sentence listing this information must appear at the beginning of the specification (see MPEP 1895.01). Appropriate correction is required.

Claim Objections

3. Claims 1-24 are objected to because they lack proper introduction. The present Office practice is to insist that each claim be the object of a sentence starting with a phrase such as "I (or we) claim" or "What is claimed is" or "That which is claimed is". See MPEP 608.01 (m). Appropriate correction is required.

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Double Patenting

4. Claims 1-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-49 of copending Application No. 08/903,978. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same amphipathic compounds and their use as adjuvants in vaccines.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. Claims 1-14 provide for the use of amphipathic compounds, and claims 21-23 recite a method for inducing an immune response, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a method or use without any active, positive steps delimiting how this method or use is actually practiced.

Claims 1-14 and 21-23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use and a method, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35

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U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC §103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popescu et al. (EPA 0 356 339) in view of Epand et al. (U.S. Patent 5,283,185).

a. Popescu et al. teach vaccine compositions comprising influenza virus hemagglutinin and liposomes of dimyristolylphosphatidylcholine (DMPC)/cholesterol (see the abstract and page 2, paragraph 1) and a method of producing an immune response by administering the vaccine composition.

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b. Epand et al. teach that some cationic amphiphiles are known to facilitate the transfer of DNA into cells, probably through enhanced binding of the DNA-lipid complex to the cell surface via the excess positive charges on the complex (column 1, lines 8-17). Epand et al. teach a method for facilitating the transfer of nucleic acids into cells with a stable aqueous dispersion comprising the nucleic acid and a dispersion of mixed lipids comprising a lipophilic group derived from cholesterol, a linker bond of a carboxamide or carbamoyl, a spacer arm of an alkyl chain, and a cationic amino group; and a co-lipid of phosphatidylcholine or phosphatidylethanolamine. Epand et al. teach the cationic lipid as selected from the group consisting of cholesteryl-3 β -carboxamidoethylenetrimethylammonium iodide, cholesteryl-3 β -carboxamidoethylethylamine, cholesteryl-3 β -oxysuccinamidoethylenetrimethylammonium iodide, 3 β -{N-(N',N'-dimethylaminoethane)-carbamoyl]-cholesterol, and 3 β -{N-(polyethyleneimine) carbonyl]-cholesterol (column 14, lines 51-68; column 15, lines 16-27; and column 16, lines 1-26).

c. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the mixed-lipid composition taught by Epand et al. in the vaccine composition of Popescu et al. for an improved adjuvant which would enhance the immune response of the target cells to the immunizing antigen by facilitating cell surface and antigen/lipid interaction.

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Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Primary Examiner Michael Woodward whose telephone number is (703) 308-3890 or Supervisory Patent Examiner Marian Knode whose telephone number is (703) 308-4311. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1815 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1815 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback

December 22, 1997

PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER
GROUP 1800